

**REMARKS**

Claims 1-12 are pending and under examination. Claims 13-18 stand withdrawn as directed to a non-elected invention. Claims 1-12 have been amended to correct grammatical errors pointed out in the claim objections as well as clarify the claimed inventions. No new matter has been added by the amendments and entry is respectfully requested.

**Regarding 35 U.S.C. §102**

The rejection of claim 1 under 35 U.S.C. §102(a) as allegedly anticipated by Fitzsimmons et al., Gene Therapy, 8:1675-1681 (2001) is respectfully traversed. The Office alleges that Fitzsimmons et al. discloses the vector of Claim 1. It is respectfully submitted that Office has not pointed out element-by-element how Fitzsimmons describes a vector of identical general structure and orientation. Accordingly, the Office has not met its burden of showing how the Fitzsimmons et al. reference anticipates the claimed invention of Claim 1. Accordingly, removal of the rejection of Claim 1 is respectfully requested.

The rejection of Claims 1, 2 and 5-12 under 35 U.S.C. §102(b) as allegedly anticipated by Nakagawa et al., European Journal of Pharmaceutical Sciences 13:53-60 (2001) is respectfully traversed. It is respectfully pointed out that, while the Office Action, at page 4, rejects claims 1, 2, and 5-12, over Nakagawa et al., only Claims 1, 5 and 8 are addressed in the rejection and concluding sentence at page 5. Clarification is respectfully requested since anticipation of a dependent claim does not follow from anticipation of a corresponding base claim. As to Claims 1, 5 and 8, it is respectfully submitted that the Nakagawa et al. reference does not anticipate the claimed vectors. Furthermore, the Office has not pointed out, element-by-element, how Nakagawa describes a recombinant vector of the claimed invention containing an insert having the general structure tTA-intron<sup>1</sup>-TK<sup>+</sup>-TetO<sub>7</sub>-CMV<sup>+</sup>-intron<sup>2</sup>-transgene. Accordingly, the Office has not met its burden and removal of the rejection is respectfully requested.

The rejection of Claims 1 and 5-12 under 35 U.S.C. §102(b) as allegedly anticipated by Straatee et al., Gene 229:21-29 (1999) is respectfully traversed. It is respectfully pointed out that, while the Office Action, at page 5, rejects claims 1 and 5-12, over Straatee et al., only

Claims 1 and 5 are addressed in the rejection and concluding sentence at page 6. Clarification is respectfully requested since anticipation of a dependent claim does not follow from anticipation of a corresponding base claim. As to Claims 1 and 5 it is respectfully submitted that the Strahtee et al. reference does not anticipate the claimed vectors. Furthermore, the Office has not pointed out, element-by-element, how Strahtee et al. describes a recombinant vector of the claimed invention containing an insert having the general structure tTA-intron<sup>1</sup>-TK<sup>+</sup>-TetO<sub>7</sub>-CMV<sup>+</sup>-intron<sup>2</sup>-transgene. Accordingly, the Office has not met its burden and removal of the rejection is respectfully requested.

### Regarding 35 U.S.C. §103

The rejection of Claims 1 and 5-12 under 35 U.S.C. §103(a) over Nakagawa et al., *supra*, in view of Lode et al., PNAS 95:2475-2480 (1998) is respectfully traversed.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974); M.P.E.P. §2143.03. As described above, the Office has not met its burden of pointing out how Nakagawa describes a recombinant vector of the claimed invention containing an insert having the general structure tTA-intron<sup>1</sup>-TK<sup>+</sup>-TetO<sub>7</sub>-CMV<sup>+</sup>-intron<sup>2</sup>-transgene. Applicant respectfully submit that the Nakagawa et al. reference does not describe or suggest a vector that contains an insert having the general structure tTA-intron<sup>1</sup>-TK<sup>+</sup>-TetO<sub>7</sub>-CMV<sup>+</sup>-intron<sup>2</sup>-transgene. This deficiency is not cured by the Lode et al. reference. Accordingly, the Office has not established a *prima facie* case and removal of the rejection of Claims 1 and 5-12 under 35 U.S.C. §103(a) over Nakagawa et al., *supra*, in view of Lode et al., PNAS 95:2475-2480 (1998) is respectfully requested.

### Regarding 35 U.S.C. §112

The rejection of claims 1-12 under 35 U.S.C. §112, second paragraph as allegedly indefinite is respectfully traversed.

A seminal case on the construction of the second paragraph of § 112 is *In re Borkowski*, 422 F.2d 904, 164 U.S.P.Q. 642 (C.C.P.A. 1970), where the CCPA observed:

The first sentence of the second paragraph of § 112 is essentially a requirement for precision and definiteness of claim language. If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

Id. at 909, 164 U.S.P.Q. at 645-46 (footnote omitted).

The Federal Circuit has since had the opportunity to decide a number of § 112, second paragraph issues. It is clear from these decisions that definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See, e.g., In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); and *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999) (district court failed to consider the knowledge of one skilled in the art when interpreting the patent disclosure).

The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe. That determination requires a construction of the claims according to the familiar canons of claim construction.

*All Dental Prodx, LLC v. Advantage Dental Prods.*, 309 F.3d 774, 779-80, 64 USPQ2d 1945, 1949 (Fed. Cir. 2002) (citations omitted).

Claim 1 is allegedly indefinite for reciting the phrase "exhibiting the general structure." Applicant submits that, viewed in light of the specification, which discloses in paragraphs [8]-[39] of the published application, what is encompassed by the general structure. Accordingly, this phrase is submitted to be sufficiently clear and definite.

Claim 2 is allegedly vague with regard to the term "reverse." The intended point of reference is allegedly unclear. Applicant submits that the recited phrase itself, which states that

the insert "is inserted into the viral vector genome in reverse orientation," clearly communicates to the skilled person that the viral vector genome is the point of reference.

Claims 2-9 are allegedly unclear for use of the term "characterized." This rejection has been rendered moot by amendment of claims 2- 9 to replace the phrase "characterized in that" with "wherein."

Claim 3 is allegedly vague because it recites the term "inverted" without a point of reference. Applicant submits that the recited phrase itself, which is "wherein the positions of tTA and transgene are inverted in the insert" makes clear that the two elements are inverted vis-à-vis each other.

Claims 9 and 10 are allegedly unclear for recitation of the term "represented" in reference to a sequence identifiers. This rejection has been rendered moot by amendment of claims 9 and 10 to replace the phrase "represented" with "designated"

Claim 10 is further rejected under 35 U.S.C. §101 for allegedly reciting a use without setting forth steps involved in the process. Claim 10 is not a use claim, but rather is a composition claim directed to an expression plasmid.

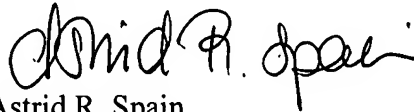
Claims 11 and 12 stand rejected for improperly claiming a use without reciting any steps. Claims 11 and 12 have been amended to address this issue, thereby rendering moot the present rejection.

In view of the above, removal of the various grounds of rejecting Claims 1-12 under 35 U.S.C. §112, second paragraph, is respectfully requested.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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